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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,147	03/24/2005	Martin J. Oliver	57767US005	6332
32692 7590 08/30/2007 3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427				
			EXAMINER	
			ALSTRUM ACEVEDO, JAMES HENRY	
			ART UNIT	PAPER NUMBER
			1616	
			NOTIFICATION DATE	DELIVERY MODE
			08/30/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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LegalDocketing@mmm.com

**Office Action Summary**

Application No.

10/510,147

Applicant(s)

OLIVER ET AL.

Examiner

James H. Alstrum-Acevedo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4-7 and 9-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7 and 9-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

**Claims 1-2, 4-7, and 9-15 are pending.** Applicants have cancelled claims 3 and 8. Applicants have amended claims 1, 12, and 15. Receipt and consideration of Applicants' amended claim set and remarks/arguments submitted on June 14, 2007 are acknowledged.

#### ***Moot Rejections/objections***

All rejections and/or objections of claims 3 and 8 cited in the previous office action mailed on December 14, 2006 **are moot**, because said claims have been cancelled.

#### ***Specification***

The objection of claim 15 because of the informalities set forth in the office action mailed on December 14, 2006 **is withdrawn**, per Applicants' claim amendments correcting said informality.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

The rejection of claims 1-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention **is withdrawn**, per Applicants' claim amendments removing the cited indefinite claim language and/or clarifying what Applicants are claiming.

*Response to Arguments*

Applicant's arguments, see page 6, filed June 14, 2007, with respect to the rejection of claims 1-15 under 35 U.S.C. 112, second paragraph, as being indefinite have been fully considered and are persuasive. The rejection of claims 1-15 under 35 U.S.C. 112, second paragraph, as being indefinite has been withdrawn.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-9, 13, and 15 under 35 U.S.C. 103(a) as being unpatentable over McNamara (WO 99/65464; IDS reference) in view of Oliver et al. (U.S. Patent No. 6,120,752) ("Oliver") and Oliver et al. (U.S. Patent No. 6,054,488) ("Oliver-488") **is maintained** for the reasons of record set forth in the office action mailed on December 14, 2006.

### ***Response to Arguments***

Applicant's arguments filed June 14, 2007 been fully considered but they are not persuasive. Applicants' have traversed the instant rejection by arguing that (1) improper hindsight was used and (2) an ordinary skilled artisan would not have had a reasonable expectation of success that one would obtain a chemically and physically stable HFA MDI formulation comprising suspended formoterol and dissolved ciclesonide due to "drug-drug interactions" and the statement that "stability is the exception not the expectation."

The Examiner respectfully disagrees with Applicants' traversal arguments. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

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Regarding argument (2), Applicants have merely argued without providing any substantive supporting evidence. The art of record clearly demonstrates that stable HFA MDI formulations comprising a dissolved steroid (e.g. beclomethasone) and a suspended betamimetic (e.g. albuterol) are known. Ciclesonide is a steroid, which has a similar active core structure relative to beclomethasone, another known anti-inflammatory steroid. Albuterol is a known betamimetic with a substituted phenol core structure and formoterol is a betamimetic with a substituted phenol core structure as well. The prior art of record is fairly suggestive of Applicants' claimed invention and provides a reasonable expectation of success. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

The rejection of claims 10-12 under 35 U.S.C. 103(a) as being unpatentable over McNamara (WO 99/65464) in view of Oliver et al. (U.S. Patent No. 6,120,752) ("Oliver") and Oliver et al. (U.S. Patent No. 6,054,488) ("Oliver-488") and further in view of Jinks et al. (WO 02/30394) **is maintained** for the reasons of record set forth in the office action mailed on December 14, 2006.

### ***Response to Arguments***

Applicant's arguments filed June 14, 2007 been fully considered but they are not persuasive. Applicants' have traversed the instant rejection by arguing that (1) improper hindsight was used and (2) an ordinary skilled artisan would not have had a reasonable

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expectation of success that one would obtain a chemically and physically stable HFA MDI formulation comprising suspended formoterol and dissolved ciclesonide due to “drug-drug interactions” and the statement that “stability is the exception not the expectation.”

The Examiner respectfully disagrees with Applicants’ traversal arguments. These traversal arguments have been rebutted above and the rebuttal is herein incorporated by reference. The instant rejection is deemed proper and is maintained.

The rejection of claim 14 under 35 U.S.C. 103(a) as being unpatentable over McNamara (WO 99/65464; IDS reference) in view of Oliver et al. (U.S. Patent No. 6,120,752) (“Oliver”) and Oliver et al. (U.S. Patent No. 6,054,488) (“Oliver-488”) as applied to claims 1-9, 13, and 15 above, and further in view of Ashurst (U.S. Patent No. 6,131,566) **is maintained** for the reasons of record set forth in the office action mailed on December 14, 2006.

### ***Response to Arguments***

Applicant's arguments filed June 14, 2007 been fully considered but they are not persuasive. Applicants’ have traversed the instant rejection by arguing that (1) improper hindsight was used and (2) an ordinary skilled artisan would not have had a reasonable expectation of success that one would obtain a chemically and physically stable HFA MDI formulation comprising suspended formoterol and dissolved ciclesonide due to “drug-drug interactions” and the statement that “stability is the exception not the expectation.”

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The Examiner respectfully disagrees with Applicants' traversal arguments. These traversal arguments have been rebutted above and the rebuttal is herein incorporated by reference. The instant rejection is deemed proper and is maintained.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Keller et al. (U.S. Patent No. 6,475,467) is considered pertinent because it discloses pharmaceutical aerosol dispersion formulations and suggests that the formulations may include other pharmaceutical active agents in solution.

**Claims 1-2, 4-7, and 9-15 are rejected. No claims are allowed.**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



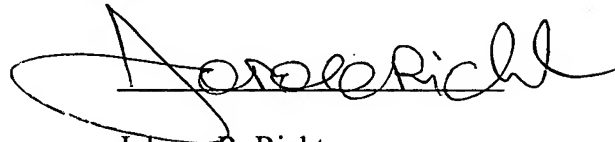
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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